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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,461	02/12/2004	Erika Hawkins	341.022US1	2264
21186	7590	11/27/2006		
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402				
			EXAMINER HANLEY, SUSAN MARIE	
			ART UNIT 1651	PAPER NUMBER

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/777,461

Applicant(s)

HAWKINS ET AL.

Examiner

Susan Hanley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-69 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/28/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

The previous restriction requirement is withdrawn and a new restriction requirement is set forth:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-42, 55, 56 and 69, drawn to methods of assaying an enzyme-mediated reaction, classified in class 435, subclass 8, for example.
- II. Claims 43-54 and 63-68, drawn to a kit, classified in class 435, subclass 975, for example.
- III. Claims 57-62, drawn to a method for reducing analyte-independent or analyte-independent phosphorescence, classified in class 250, subclass 252.1, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I or III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the methods can be practiced without the kit and the kit components can be used for assaying non-luminescent reactions.

Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the enzyme assay can be carried out without reducing background phosphorescence or the contribution of the background phosphorescence can be subtracted out by using a blank. The subcombination has separate utility such as employing it to reduced background phosphorescence in photoreactions.

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Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species

This application contains claims directed to the following patentably distinct species:

If Group I is elected, the following specie elections are required:

A. For the FIRST OR SECOND enzyme-mediated luminescence reaction, elect a quenching agent from the following:

1. a sequestering agent; if this specie is elected, Applicant is further required to elect one of the following: a nonionic detergent, a crown ether, a glycol or a cyclodextrin.
2. a colored compound; if this specie is elected, Applicant is further required to elect the type of light that is quenched: red, blue, or green.
3. a substrate analog inhibitor that is a protected coelenterazine.

The species are independent or distinct because they have chemical structure that are distinct from one another. The distinct structures cause the compounds to have unrelated properties that cause the quenching.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-4, 12, 13, 17-42 are generic.

B. For the FIRST enzyme-mediated luminescence reaction, Applicant is required to elect if the luminescence reaction is:

1. peroxidase-mediated luminescence reaction;
2. ° phosphatase-mediated luminescence reaction; or
3. luciferase-mediated; if this specie is elected, Applicant is required to elect the type of luciferase mediation from one of the following:

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a. anthozoan luciferase;

b. *Renilla reniformis*.

The species are independent or distinct because enzymes have different chemical structures with at least three levels of complexity. This causes enzymes to catalyze reactions by different mechanisms and to have different substrate specificities.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-5, 6-11, 16, 20-24, 29-32, 35, 37-42, 55, 56 and 60 are generic.

C. For the SECOND enzyme-mediated luminescence reaction, Applicant is required to elect if the luminescence reaction is:

1. peroxidase-mediated luminescence reaction;
2. phosphatase-mediated luminescence reaction; or
3. luciferase-mediated; if this specie is elected, Applicant is required to elect the type of luciferase mediation from one of the following:
 - a. anthozoan luciferase;
 - b. *Renilla reniformis*;
 - c. *Photinus pyralis* luciferase; or
 - d. *Pyrophorous plagiophthalmus* luciferase.

The species are independent or distinct because enzymes have different chemical structures with at least three levels of complexity. This causes enzymes to catalyze reactions by different mechanisms and to have different substrate specificities.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-19, 24-28, 36-4255, 56 and 60 are generic.

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If Group II is elected, the following specie elections are required:

A. Applicant is required to elect a quenching agent from one of the following:

1. a sequestering agent, if this specie is elected, Applicant is further required to elect one of the following: a nonionic detergent, a crown ether, a glycol or a cyclodextrin;
2. a colored compound, if this specie is elected, Applicant is further required to elect the type of light that is quenched: red, blue, or green;
3. a substrate analog inhibitor that is a protected coelenterazine.

The species are independent or distinct because they have chemical structure that are distinct from one another. They distinct structures cause the compounds to have unrelated properties that cause the quenching.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 44, 49-51, and 63-67 are generic.

If Group III is elected, Applicant is required to make the following specie elections:

I. Elect if the colored compound is red, blue yellow or green.

The species are independent or distinct because the chemical structure of a colored compound is dependent on wavelength of light that the compound reflects.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 57-59, 61 and 62 are generic.

II. Applicant is required to elect if the enzyme is an anthozoan or beetle luciferase.

The species are independent or distinct because enzymes have different chemical structures with at least three levels of complexity. This causes enzymes to catalyze reactions by different mechanisms and to have different substrate specificities.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, claims 57-60 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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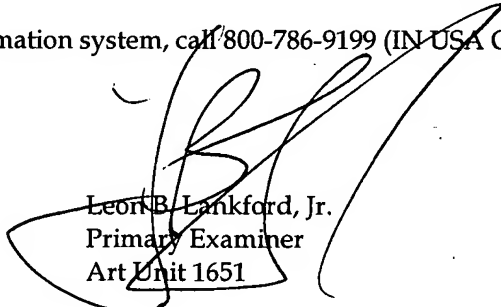
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan Hanley
Patent Examiner
AU 1651



Leon B. Lankford, Jr.
Primary Examiner
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